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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/577,359

Applicant(s)

GREGORY ET AL.

Examiner

NANCY BITAR

Art Unit

2624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-44 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 28 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's response to the last Office Action, filed 12/22/2008, has been entered and made of record.
2. Applicant has amended claims 1-18. Claims 19-44 have been added. Claims 1-44 are currently pending.
3. Applicant's arguments, in the amendment filed 3/23/2009, with respect to the rejections of claims 1-18 under 35 U.S.C.103 (a) have been fully considered but are moot in view of the new ground(s) of rejection necessitated by the amendments. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Lang et al. (US 2005/0010106)

Examiner Notes

Examiner cites particular columns and line numbers in the references as applied to the claims below for the convenience of the applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply as well. It is respectfully requested that, in preparing responses, the applicant fully consider the references in entirety as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the examiner

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-5; 12-18 are rejected under 35 U.S.C. 103(a) as being anticipated by Mazess et al (WO 94/06351) in view of Lang et al. (US 2005/0010106)

As to claim 1, Mazess et al teaches an apparatus for predicting bone fracture risk in an osteoporotic patient (figure 1), which apparatus comprises

a Dual X-ray Absorptiometry scanner for scanning a body area of the patient and producing a Dual X-ray Absorptiometry image of the body part within said body area (dual energy x-ray densometers to permit measurement of bone density; page 8, lines 5-15); an image analysis module configured to perform shape and texture analysis of the dual x-ray absorptiometry image to thereby generate an image data representative of aspects of the shape of the body part and the structure of bone within the body area (computer is programmed to use the data regarding shape and size to formulate indicia of vertebral condition having clinical and diagnostic value and then to visually display the indicia ; page 24 , lines 7-29); and a data comparison means comprising a database of comparative data sets from Dual X-ray Absorptiometry images of control subjects, for comparison with the image data set generated from the Dual X-ray Absorptiometry image of the patient (page 32 , lines 28-31), to thereby

predict the risk of bone fracture in the patient (page 30, line 20 to page 31, line 4, claim 32).

While Mazess meets a number of the limitations of the claimed invention, as pointed out more fully above, Mazess fails to specifically teach a module configured to perform shape and texture analysis of the DXA images to generate an image data set. Specifically, Lang et al teaches the use of discriminant analysis to compare the patient data set with the image data sets of the control subject and deriving information regarding one or more bone parameters from an image comprising: (a) obtaining an image comprising bone from a subject; (b) defining two or more regions of interest (ROIs) in the image; and (c) analyzing a plurality of positions in the ROIs to determine one or more parameters selected from the group consisting of bone microarchitecture, bone macro-anatomy, biomechanical parameters and combinations thereof of the ROIs (paragraph [00309-00312]; see also paragraph [00287-00288])). It would have been obvious to one of ordinary skill in the art to use the discrimination analysis (i.e. comparison method) in the Dual X-ray absorption scanner in order to allow for the accurate and reliable evaluation of bone structure and macro-anatomical parameters from x-ray images. . Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention by applicant.

As to claim 2, Lang et al teaches the apparatus according to claim 1, wherein the body part is a proximal femur (The outline of the rescaled model is then used as the initial template and is positioned within the proximal femur in the input image, paragraph [0308])

As to claim 3, Mazess et al teaches the apparatus of claim 1 configured to analyze different body parts (figure 1)

As to claim 4, Mazess the apparatus according to claim 1 configures to analyze more than one of proximal femur, wrist, ankle, hand and spine (see figure 2; pages 13-14).

As to claim 5, Lang teaches the apparatus according to claim 1 wherein the image analysis module is configured to analyze aspects of the dual x-ray absorptiometry image using an active shape model to generate an active shape model data act representative of the shape of the body part (regularized active shape algorithm can be used , paragraph [0308])

As to claim 6-8, Lang teaches the image analysis means analyses the Dual X-ray Absorptiometry image by analysis of the texture of the body part and the analysis of the texture of the body part uses Fourier transforms and Principal Component Analysis (A different approach to analyze the texture in an image is by fractal analysis., Fourier analysis (paragraph [0172-0176])

As to claim 9, Mazess teaches the apparatus of claim 1, configured to compare I) a value obtained from comparison of the image data set for the dual x-ray absorptiometry image of the patient or subject with the database of comparative data sets with bone mineral density data obtained from the dual x-ray absorptiometry image (claim 32; see also Lang et al, paragraph [0058]).

The limitation of claim 10 has been addressed above except for the following: providing a measure of the progression of the disorder in the patient". Lang et al teaches in paragraph [0246] where treatment or monitoring of treatment of bone related disorders are provided.

As to claim 11, Lang teaches that the disorder is osteoarthritis (methods of monitoring bone structure and/or macro-anatomical and/or biomechanical parameters over time (e.g.

Longitudinally) are also provided, for example to assess progression of osteoporosis and/or response to therapy, paragraph [0234])

As to claim 12, Liang teaches that the disorder is a Paget disease. (Paget's disease, paragraph [0238]).

The limitation of claims 13-20 has been addressed in claims 2-9.

The limitation of claim 21 has been addressed above except for the following: "predicting the risk of osteoarthritis in the patient". Liang teaches methods of diagnosing or predicting bone-related disorders (e.g., osteoporosis, Paget's disease, osteogenesis imperfecta, bone cancers), periodontal disease or oral implant failure in a subject are provided, for example using any of the kits, methods and/or devices described herein. It will be apparent that these methods are applicable to any bone-related disorder including, for example, osteoporosis, bone cancer, and the like, as well as to periodontal disease and implant failure. (Section 4.2 paragraph [0238-0243])

The limitation of claims 22-29 has been addressed in claims 2-9.

The limitation of claim 30 has been addressed above except for the following: "provide a measure of non-pathological changes associated with age, gender, body mass index or genetics". Liang teaches data attributes can be input by the subject and/or operator, for example subject identifiers, i.e. characteristics associated with a particular subject. These identifiers include but are not limited to the following: (1) a subject code (e.g., a numeric or alpha-numeric sequence); (2) demographic information such as race, gender and age; (3) physical characteristics such as

Weight, height and body mass index (BMI); (4) selected aspects of the subject's medical history (e.g., disease states or conditions, etc.); and (5) disease-associated characteristics such as the type of bone disorder, if any; the type of medication used by the subject. In the practice of the present Invention, each data point would typically be identified with the particular subject, as well as the demographic, etc. characteristic of that subject (paragraph [090] and paragraph [0250])

The limitation of claims 31-38 has been addressed above.

The limitation of claim 39 has been addressed above except for the following:”
quantifying deformation of a proximal femur of a patient “. Lang et al teaches in FIG. 14 illustrate the propagation of the initial control points towards the femur edge. When the iteration is completed, a deformation field for the model area is calculated and quantified. This deformation field is interpolated for the model ROI inside the boundaries of the femur model. The result is a new set of ROI that is adapted to the input image, but similar to the model ROI with respect to anatomical landmarks (see FIG. 9). Note that each of claims 10, 21, 30, and 39 are several prediction methods that are used in the same apparatus that helps in improving prediction quality.

The limitation of claims 40-44 has been addressed above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY BITAR whose telephone number is (571)270-1041. The examiner can normally be reached on Mon-Fri (7:30a.m. to 5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vikkram Bali can be reached on 571-272-7415. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nancy Bitar/
Examiner, Art Unit 2624

/Vikkram Bali/
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